

## **II. REMARKS**

### **A. Status of the Claims**

Claims 19-25, 38-41, 43-65, and 78-85 were currently under consideration at the time of the Office Action. Claims 40 and 46 have been amended in the Amendment set forth herein. No new claims have been added, and no additional claims have been canceled. Therefore, claims 19-25, 38-41, 43-65, and 78-85 are currently under consideration.

### **B. Interview with Examiner Ketter**

Applicant's representative, Monica De La Paz, spoke with Examiner James S. Ketter today by telephone on June 15, 2006. The subject matter of the teleconference was the Office Action faxed to Applicants' representative, Monica De La Paz, on June 12, 2006. Examiner Ketter indicated that the Office Action faxed to Applicant's representative, Monica De La Paz, on June 12, 2006, which did not include a cover sheet showing a date of mailing, evidences that prosecution has been reopened, and that the Office Action would be formally mailed from the U.S.P.T.O. on June 16, 2006, to Applicants' representative. Examiner Ketter also indicated that he would complete an Examiner's Interview Summary setting forth that he has reopened prosecution prior to June 15, 2006, as further evidence the prosecution has been reopened. He stated that in view of the Office Action faxed on June 12, 2006, and his Interview Summary, that this application would not go abandoned if a Notice of Appeal was not filed by June 15, 2006, because prosecution has been reopened. Examiner Ketter spoke to his Supervisory Examiner today, who concurred that the case would not go abandoned because prosecution has been reopened.

On June 21, 2006, Applicants received by mail a copy of the Office Action faxed to Applicants on June 12, 2006. The date mailed was June 16, 2006.

**C. The Claim Rejections Under 35 U.S.C. §101 are Overcome**

Claims 19-25, 38-41, 43-65, and 78-85 have been rejected under 35 U.S.C. §101 because the claimed invention is alleged to lack patentable utility. More particularly, the Examiner argues that it is not apparent “what useful outcome is produced by possessing the expression data thus generated.” Applicants respectfully traverse this rejection, and respond as follows.

The specification clearly sets forth that the claimed methods of detecting recombinant somatostatin receptors have utility in a variety of contexts. Examples of these utilities are set forth as follows:

- The claimed invention is of benefit in assessing sites within a patient’s body where gene expression is occurring following gene therapy administration in a subject (specification, paragraph [0003] and [0010])
- The claimed invention is of benefit in quantifying gene expression in a subject following administration of gene therapy, which can be used in assessing therapeutic effectiveness (specification, paragraph [0003] and [0010]).
- The claimed invention is of benefit in determining the duration of gene expression in a subject following administration of gene therapy, which can be used in assessing therapeutic effectiveness (specification, paragraphs [0003] and [0010]).
- The benefit over existing methods of monitoring gene therapy in humans is that radiopharmaceuticals and radioisotopes, which are not known to be safe in humans and which may have unforeseen adverse consequences, can be avoided. (specification, paragraph [0003]).
- The claimed methods can be applied in quantifying gene transfer *in vitro* (specification, paragraph [0006]), and thus allows for comparison of gene

expression *in vitro* with expression *in vivo* to facilitate the development of recombinant somatostatin receptors with improved ligand binding capability (specification, [paragraph 0010]).

- The claimed methods allow for localization of gene transfer to particular subcellular locations (specification, paragraph [0008])
- The claimed methods allows for localization of gene transfer to tissue without destruction of cells [specification, paragraph [0008]].
- The recombinant somatostatin receptors can be constructed such that they do not interfere with receptor internalization (specification, paragraph [0075])
- Fusion of recombinant somatostatin receptors to protein tags allows for multiple binding ligand binding sites that can be used in confirmation of gene expression (paragraph [0077])
- The methods of the present invention can be applied to specifically localize a radiopharmaceutical to a particular site in a subject (specification, paragraph [0079])

In view of the above, the claimed invention does not lack patentable utility. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. §101 should be WITHDRAWN.

**D. The Rejections Under 35 U.S.C. §112, Second Paragraph, Are Overcome**

Claims 40 and 46 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

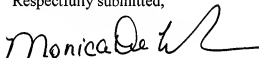
Applicants regard as the invention. In particular, the instant claims have been rejected as employing incorrect Markush-type language for reciting "or" instead of "and." In the Amendment set forth herein, Applicants have amended claims 40 and 46 to correct the typographical error and recite "and" instead of "or." Exemplary support for the amendments to these claims can be found in paragraph [0007] of the specification.

In view of the above, it is respectfully submitted that this rejection should be WITHDRAWN.

**E. Conclusion**

In view of the above, Applicant respectfully submits that each of the rejections in the Office Action have been overcome, and that all claims are in condition for allowance. The Examiner is invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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